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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,280	11/12/2003	Patrick Guiney	11.037011 US	9311

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EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	PAPER NUMBER
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,280	GUINEY, PATRICK	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43 and 51-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43 and 51-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/5/04, 1/31/05, 1/3/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REMARKS

Claims 1-56 were pending. In response to the restriction requirement, Applicant elected the prosecution of claims 1-43 and cancelled claims 44-50. Examiner agrees with Applicant that claims 51-56 were erroneously included in claim group II. Claims 51-56 were intended to be included in claim group I, and they will be examined on the merits along with claims 1-43.

The amendments to claims 18 and 53 to correct minor informalities have been acknowledged.

Claim Objections

Claim 40 is objected to because of the following informalities:

"interface" should be changed to "interfaces".

Claim 53 is objected to because of the following informalities:

"data storage device of the filter" should be changed to "data storage device associated with the filter". The claim never established that the filter comprises the data storage device.

Claim 54 is objected to because of the following informalities:

Similar to the objection to claim 53, the claim never established that the filter comprises or relays data.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **4 and 21** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "liquid-based" is indefinite. "liquid-based" does not appear to be a term that is used frequently in the art, and the Specification does not define what constitutes a "liquid-based filter". The Specification gives an example of such a filter, but the example does not sufficiently define a "liquid-based filter". It is not clear whether the term is intended to convey that the filter is made from a liquid substance, or if the filter is designed to collect liquid samples.

For purposes of examination, it will be assumed that the filter is designed to collect liquid samples.

Claims **39-42** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 does not positively recite that the claimed system comprises a vial. The claim recites the vial via its relationship with the specimen, but the specimen is not a part of the claimed system. Therefore, it is not clear whether Applicant intended the vial to further limit the structure of the claimed system. Because the claim does not positively recite the vial, the structural relationship of the vial with respect to the system is indefinite from the language of the claims.

For purposes of examination, because the claims do not positively recite a vial, limitations directed towards the vial will be considered non-limiting.

Claims **52-55** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims do not positively recite that the claimed apparatus comprises the slide processor (claim 52), a vial (claim 54), or a unique number (claim 55). Therefore, it is unclear whether the limitations directed towards the slide processor, the vial and the unique number are limiting.

For purposes of examination, because the claims do not positively recite these features, limitations directed towards these features will be considered non-limiting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **1, 3, 6, 7, 12, 18, 20, 23, 24, 29, 31, 35-37, 39, 40 and 51-55** are rejected under 35 U.S.C. 102(e) as being anticipated by Morrison (US 2004/0126281 A1).

Morrison discloses a sample analysis system comprising a tray-like specimen container 10 comprising a filter 14 and a memory that stores data related to the sample stored in the container (see Fig. 1 and [0032]). The data stored in the memory can comprise the number of times the sample has been accessed, including the time and date of each accession and/or sample identification.

With respect to claim 7, although the reference does not explicitly disclose the location of the memory with respect to the sample container, the reference discloses that the memory is accessed when the container is interfaced or docked with a testing apparatus (see [0032]). Based on the disclosure, it is evident that at least a portion of the memory is disposed at the surface of the sample container where the container interfaces with the testing apparatus.

With respect to the processor and its relationship to the data storage device, Morrison does not explicitly disclose a processor. Nonetheless, it is evident that the system disclosed by Morrison comprises a processor. Without a processor, the data stored in the memory could not be retrieved. Furthermore, Morrison discloses that the memory may be a form of electronic memory such as a non-volatile RAM, which is updated upon docking with the testing apparatus (see [0032]). It is well known that non-volatile RAMs, such as USB flash drives, work only when it interfaces with a processor that is capable of accessing the data stored in the flash drive. Therefore, even though

Morrison does not disclose a processor, it is evident from the disclosure that the system disclosed by Morrison houses a processor, and that the non-volatile RAM communicates with a processor disposed in the testing apparatus by the docking or interfacing means.

Claims **1, 5, 11, 14, 15, 18, 22, 30, 31, 33, 34, 38, 39, 40 and 52-55** are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey (US 5,635,403).

Bailey discloses a sample collecting container 86 comprising a filter 102 and a data storage device 90 associated with the container (see Figs. 8 and 9). The data storage device 90 is a computer, which comprises read only memory (ROM) and it interfaces with the filter by means of a wireless communication interface 92 such as a bar code reader. The data stored and processed by the computer comprises identification of the sample and the tests to be performed on the sample (see lines 40-65, col. 7).

Although the reference does not explicitly disclose that the stored data comprises the number of steps involved in processing the sample, it is evident that the data comprises this information based on the disclosure that the data comprises the tests to be performed on the sample. If the data did not comprise the method steps of the test to be performed, the test could not be performed.

Claims **1-7, 11, 12, 14, 15, 18-24, 30, 31, 33, 34, 36, 38, 39-42 and 51-55** are rejected under 35 U.S.C. 102(b) as being anticipated by McDevitt et al. (US 2002/0045272 A1).

McDevitt et al. disclose an Analyte Detection Device (ADD) comprising a tray-like substrate having an array of wells (see Fig. 3), wherein each well can comprise a filter for processing blood samples (see [0464]). The ADD comprises a detector and a means for processing and producing data regarding the analytes (see [0431]). The substrate can comprise a bar code for identifying the contents of the wells, and relaying test protocols to a computer (see [0573], [0574]). The ADD may also be connected wirelessly, via a floppy drive, or a serial data connection to a network of computers to send and receive data (see [0438]).

With respect to claims 14 and 33, although the reference does not explicitly disclose that the bar code disclosed by McDevitt et al. relays the number of steps involved in the test protocols, it is evident that the bar code relays this information. If the bar code did not relay the method steps of the test to be performed, then the test could not be performed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **16, 17, 35, 43 and 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al.

With respect claims 16 and 35, it is well known in the art that most electronic products such as computers are assigned a universal product code or another form of product identification number to facilitate the identification of the product. Therefore, it would have been obvious to assign a unique registration number to the data storage means of the ADD so that it can be easily identified in case that it has to be replaced.

With respect to claims 17, 43 and 56, given that the ADD is intended to process blood samples, which contain blood cells, it would have been obvious to one of ordinary skill in the art to use a cytological filter to support the blood sample.

Claims **8-10 and 25-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al. in view of Marsh et al. (US 5,219,294).

McDevitt et al. do not disclose the details of the connection between the ADD and a computer. However, it does disclose that the ADD can be connected to a computer system via well-known means (see [0438]).

Marsh et al. disclose a docking connector for connecting two electrical devices (i.e. computer and printer). The docking connector comprises a symmetrical recess comprising tapered surfaces 38a and 38b to ensure a solid physical connection (see Figs 1 and 6 and line 51, col. 3).

In light of the disclosure of Marsh et al., it would have been obvious to one of ordinary skill in the art to design the interface connection of the ADD disclosed by McDevitt et al. such that it can accommodate the connector disclosed by Marsh et al. so that the ADD can send and receive data from a computer. To accommodate the connector disclosed by Marsh et al., the ADD would need to comprise an interface having a symmetrical recess with tapered surfaces.

Claims **13, 16, 32 and 35** are rejected under U.S.C. 103(a) as being unpatentable over Bailey.

Although the reference does not explicitly disclose that the data comprises whether the filter has expired, the reference does disclose that the data comprises the time of each sampling initiation and termination and the air flow rate through each sampling means (see lines 50-55, col. 7). It appears that the data comprises sufficient information to calculate whether the filter has expired, and logically it would have been obvious to determine whether the filter has expired so that the data extracted from an expired filter does not skew the overall data collected from the functional filters. The reference discloses that one of the principal purposes of collecting the samples is to construct data regarding contamination exposure at workplaces where hazardous

materials are prevalent, and that minimizing data collection error caused by outliers is crucial in achieving this purpose (see line 60, column 1-line 55, column 2).

With respect to the registration number, it is well known in the art that most electronic products are assigned a universal product code or another form of product identification number to facilitate the identification of the product. It would have been obvious to assign a unique registration number to the memory means so that the memory means can be easily identified.

Claims **16, 17, 35, 43 and 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison.

With respect to the registration number, it is well known in the art that most electronic products are assigned a universal product code or another form of product identification number to facilitate the identification of the product. It is evident that the memory means disclosed by Morrison comprises a unique registration number. In the alternative, it would have been obvious to assign a unique registration number to the memory means so that the memory means can be easily identified.

With respect to claims 17, 43 and 56, although the reference does no explicitly disclose that the filter is a cytological filter, given that the sample container is intended to hold blood (see [0013]), which contains blood cells, it would have been obvious to one of ordinary skill in the art to use a cytological filter to support the blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
3/2/07

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